

# FDA and the Reuse of Single Use Devices: Policy Now Established

Larry Kessler, Sc.D.

Director

Office of Surveillance and Biometrics

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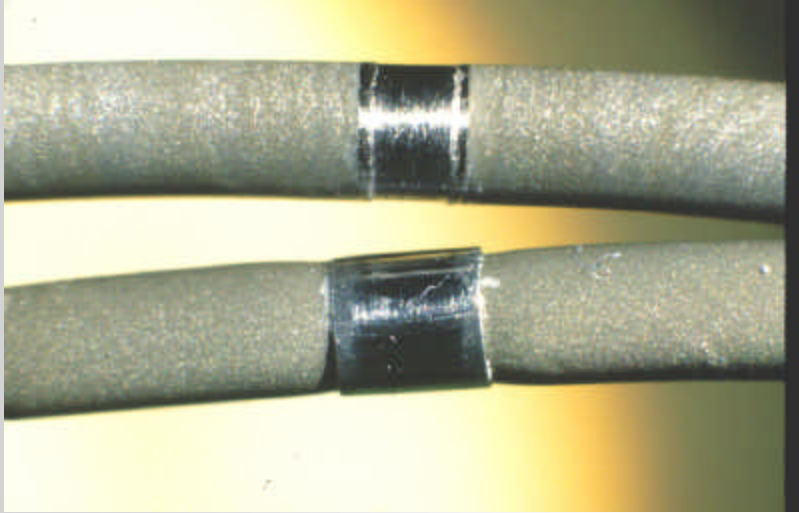
# Objectives of Presentation

- Explain how we arrived at this issue
- Describe FDA's now “finalized” regulatory strategy
- Describe efforts still ongoing at the FDA to resolve the reuse area

# Why Deal with this Issue

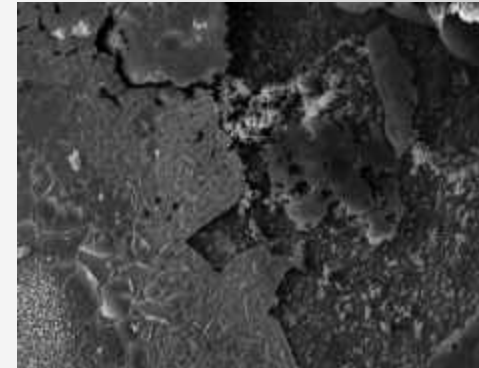
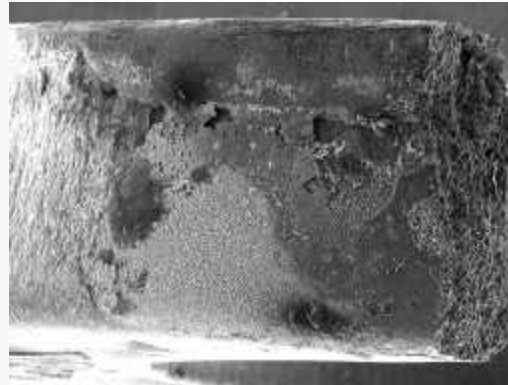
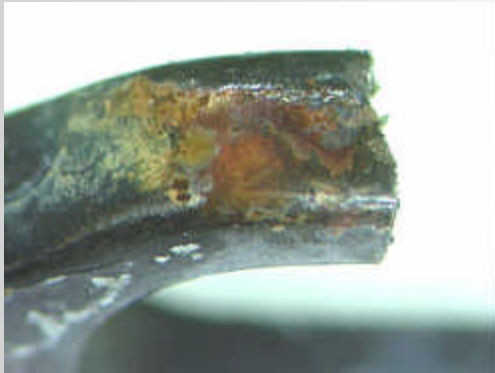
- Identical regulatory controls
  - *Reprocessing IS manufacturing*
- Public concern
- FDA research shows reprocessing may be feasible, but is difficult and possibly *dangerous*
  - Minimal evidence of problems does not mean the current practice is safe and effective





# Validation of Materials

- Metal used for SUD jaws: Modification of the heat treatment process made device more robust for the first use but caused cracking when reprocessed due to *stress corrosion cracking and hydrogen embrittlement*



⇒ Refurbishers have to understand materials and manufacturing process

# Design, Validation & QS

- SUD's are validated and designed for one use
  - Materials selected for single use
  - Biocompatibility ensured for intended environment
  - Devices are subjected to miniaturisation
  - OEM's validation and performance testing is limited to initial failure



# EP Catheter Incident

Product: EP catheter with tip electrode and several ring electrodes used for diagnostic and ablation

Reprocessed 3 times by 3<sup>rd</sup> party reprocessing firm in Germany, although evidence of the failure mode was available

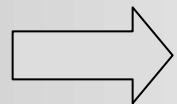


Electrodes separated - moved distally - heart valve trapped between both Electrodes. Catheter had to be pulled back by using extensive force which damaged the heart valve.



# EP Catheters

- Comparison of new and reprocessed catheter tips
- Implantation into the jugular veins of dogs  
*standard in vivo thrombogenicity tests*
- Result of NAMSA analysis
  - New catheter, 4 hours: minimal thrombosis
  - Refurbished catheter, 2 hours: slight to moderate thrombosis



Reprocessed devices which are not adequately cleaned pose a measurable higher risk to patients

# Areas of Laboratory Evaluation

- **Cleaning of devices**
- **Device functionality after reprocessing**
- **Material changes due to reprocessing**
- **Standards Development at AAMI**
  - “Sterilization of medical devices - Requirements for products labeled ‘Sterile’” under revision
  - “Bacterial Endotoxin - Test Methodologies ...” is out for comment
  - New standard on “Cleaning of Medical Devices” - Working group met 11/15/2000

# Current Guidance and Plans

- Guidance issued August 14, 2000
- Third party reproprocessors: remain under all non-premarket provisions of FD&C Act
- Hospitals: Have one year from final date of guidance for non-premarket compliance
  - Hospital inspections via FDA inspectors
- Premarket submissions will begin in Feb. 2001

# Premarket Submissions by Risk

## Device Class

## Submission Date

Class III

February, 2001

Class II

August, 2001

Class I

February, 2002

# Issues Still in Development

- Guidance for premarket submissions
- Guidance for GMP/QSR inspection
- “High-risk” exempt products: should they maintain their exemption
- Open but unused devices
- Labeling issues
  - For the reprocessed product
  - For the original equipment manufacturer (OEM)
- Health care facilities other than hospitals

# General Approach to Premarket Review

- We are evaluating a new device, not a process for 510(k)s and PMAs
- Apply the same procedures and guidance as for any other new device in least burdensome manner
- New device *can be* single use or reusable
- Reuse *not a new intended use*

# Some Technical Concerns

- Control of “raw material”
- Defining the specifications
- Identification of changes to OEM device
- Cleaning and sterilization procedures
- Functionality of a reprocessed device
- Bundling of submissions
- Labeling: especially with OEM imprinting



# Inspection Authority & Focus

- Authority: Section 704 of the Federal Food, Drug and Cosmetic (FD&C) Act
- Primary Focus: Quality System Regulation, 21 CFR Part 820
- Other Areas of Focus:
  - Medical Device Reporting, 21 CFR Part 803
  - Corrections and Removals, 21 CFR Part 806
  - Tracking, 21 CFR Part 821
  - Labeling, 21 CFR Part 801
  - Premarket Requirements, 21 CFR 807 and 814

# Who Will Conduct Inspections?

- FDA for Third-Party Reprocessors
- FDA for hospitals !
- Hospital inspections possible by JCAHO for those who stay in the business of reprocessing “high risk” products – but this is voluntary from JCAHO

# Key Elements of Quality System Regulation

- Management Controls
- Design Controls
- Corrective and Preventive Actions
- Production and Process Controls

# Where Do We Go From Here?

- Non-Premarket Requirements in Effect Now for Third Parties and in One Year for Hospitals
- Developing Inspection Guidance
- All Third-Party Reprocessors will be inspected in FY 20001

# Where Do We Go From Here?

- Early inspections/audits of hospitals will be focused on education - not enforcement
- Inspection emphasis on SUDs representing greater risk after reprocessing, more likely the Class II and III products initially

# Vision for the Future

## Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful; don't identify vulnerabilities
- Patients are not informed - experimentation?

## Future Vision

- FDA approach will be risk and science based
- Premarket submissions for Class III required as of February 14, 2001
- Premarket for Class II, August 14, 2001
- Horizontal and vertical standards could be useful
- Substantial outreach